



UNITED STATES PATENT AND TRADEMARK OFFICE

35 U.S.C. § 112: Supplemental Examination Guidelines

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Source

- Supplementary Examination Guidelines for Determining Compliance with 35 U.S.C. Section 112 and for Treatment of Related Issues in Patent Applications 76 FR 7162 (Feb. 9, 2011) (Hereinafter: “**Supplemental 112 Guidelines**”) available at <http://www.uspto.gov/patents/law/notices/2011.jsp>. ;
- For Specific 112 ¶ 2 Examples: See §2173.05
 - Examples of claim language which have been held to be indefinite set forth in MPEP § 2173.05(d) are “fact specific and should not be applied as per se rules.” [Emphasis in MPEP]



Claim Interpretation: MPEP § 2111

- During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. en banc: 2005) (the "BRI" test);
- Words of a claim must be given their "Plain Meaning" unless such meaning is inconsistent with the specification.
 - "Plain Meaning" refers to the ordinary and customary meaning given to the term by those of ordinary skill in the art.
 - Applicant may be own lexicographer.



Definiteness Test

- “The test for definiteness under 35 U.S.C. § 112, second paragraph, is whether “those skilled in the art would understand what is claimed when the claim is read in light of the specification.” *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986) (citations omitted).” MPEP § 2173.02.
- “The primary purpose of the definiteness requirement for claim language is to ensure that the scope of the claims is clear so that the public is informed of the boundaries of what constitutes infringement of the patent.” (the metes and bounds of the claim). Supplemental Guidelines.



Analyzing Claims for Indefiniteness

“Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) the content of the particular application disclosure;
- (B) the teachings of the prior art; and
- (C) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.”

MPEP 2173.02



Two or More Plausible Constructions

- If a claim is amenable to two or more plausible constructions, applicant is required to amend the claim to more precisely define the metes and bounds of the claimed invention or the claim is indefinite under § 112, ¶ 2. *Ex parte Miyazaki*, 89 USPQ2d 1207 (BPAI 2008) (expanded panel).
- “Where the claim is subject to more than one interpretation and at least one interpretation would render the claim unpatentable over the prior art, the examiner should reject the claim as indefinite under 35 U.S.C. ¶ 112, second paragraph, and should reject the claim over the prior art based on the interpretation of the claim that renders the prior art applicable.”
 - From 9/2/08 Memo entitled “Indefiniteness Rejections under 35 USC 112, 2nd Paragraph”, page 2/5 at http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/section_112_2nd_09_02_2008.pdf



Lack of Antecedent Basis

- A claim is indefinite when it contains words or phrases whose meaning is unclear.
- Could arise where a claim refers to “said lever” or “the lever”, where:
 - the claim contains no earlier lever limitation and it’s unclear as to what is being referenced ; or
 - if two different levers are earlier recited and it is uncertain as to which is being referenced.
- See MPEP 2173.05(e).



Antecedent Basis: Example 1

1. A cosmetic skin-treating composition comprising;
an anti-oxidant; an emollient; and a preservative.
 2. The composition according to claim 1, wherein the stability enhancing constant of the preservative is 5.
- A 112/2 rejection of claim 2 should not be made for lack of antecedent basis regarding “the stability enhancing constant” since it is clear that this property is referring to “the preservative” of claim 1.
 - “Obviously, however, the failure to provide explicit antecedent basis for terms does not always render a claim indefinite.” MPEP 2173.05(e)



Antecedent Basis: Example 2

1. A multilayer article, comprising a core and at least one elastomer layer.
 2. A multilayer article according to claim 1, wherein the elastomer layer comprises thermoplastic polyurethane.
- A 112/2 rejection of claim 2 should be made for lack of antecedent basis regarding the unclear scope of “the elastomer layer” since:
 - in claim 1, “at least one elastomer layer”, encompasses multiple elastomer layers; and
 - it is unclear whether just one, more than one, or all elastomer layers comprise thermoplastic polyurethane.



“Terms of Degree” and “Relative Terminology”

- MPEP 2173.05 (b)
- When a term of degree is present
 - Ask: Would one of ordinary skill in the art be apprised of the claim scope ? In other words, is there a disclosed standard for determining degree?
 - If Yes: don't make a 112 2nd rejection;
 - If No: consider making a 112 2nd rejection.



“Terms of Degree” and “Relative Terminology”: Fact-Specific Inquiry

- The phrase “substantial portion” was held to be indefinite because the specification lacked some standard for measuring the degree intended. *Ex parte Oetiker*, 23 USPQ2d 1641 (Bd. Pat. App. & Inter. 1992).
- Contrast: with the CCPA holding that the limitation “to substantially increase the efficiency of the compound as a copper extractant” was definite in view of the general guidelines contained in the specification. *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975).
- See MPEP 2173.05.



Term of Degree: “ at least about ... ”

- No *Per Se* Rules:
 - Example 1: Indefinite: *Amgen v. Chugai* (CAFC);
 - Example 2: Definite: *Ex parte Hrkach* (BPAI).



Term of Degree: Example 1 (“at least about”)

- Claim 4. Homogeneous erythropoietin characterized by a molecular weight of about 34,000 daltons on SDS PAGE, movement as a single peak on reverse phase high performance liquid chromatography and a specific activity of at least about 160,000 IU per absorbance unit at 280 nanometers.
- Amgen v. Chugai 18 USPQ2d 1016, 1030 (Fed Cir 1991).



Term of Degree: Example 1 (“at least about”) *cont.*

CAFC: the term "at least about" was found indefinite where there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term about".

(“Because...the term 'about' 160,000 gives no hint as to which mean value between the *Miyake et al.* value of 128,620 and the mean specific activity level of 160,000 constitutes infringement," the court held the "at least about" claims to be invalid for indefiniteness. 13 USPQ2d at 1787-88. This holding was further supported by the fact that nothing in the specification, prosecution history, or prior art provides any indication as to what range of specific activity is covered by the term "about," and by the fact that no expert testified as to a definite meaning for the term in the context of the prior art.” See 18 USPQ2d at 1030).



Term of Degree: Example 2 (“at least about”)

- Claim 43. A method of delivering an agent to the pulmonary system of a compromised patient having a peak inspiratory flow rate of less than about 20 liters per minute, in a single breath-activated step, comprising administering a particle mass comprising an agent from a dry powder inhaler having a receptacle containing less than 5 milligrams of the mass, and wherein the lung deposition in the patient of the total dose of the mass in the receptacle is at least about 50%
- Based on *Ex parte JEFFREY S. HRKACH*; Appeal 2010-000380 (BPAI: decided February 11, 2011) pages 1-10.



Term of Degree: Example 2 (“at least about”) cont.

- Board Held: “While we agree ... that the Specification does not define the term “about” ... we conclude that the metes and bounds of the claims would be reasonably clear to the skilled artisan ... We acknowledge that the phrase “at least about 160,000” has been held to be indefinite based on a specific set of facts, see *Amgen Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1218 (Fed. Cir. 1991). **However, the Amgen court specifically “caution[ed] that [its] holding that the term ‘about’ renders indefinite claims 4 and 6 should not be understood as ruling out any and all uses of this term in patent claims. It may be acceptable in appropriate fact situations..., even though it is not here.”** *Id.* (emphasis provided). The Examiner has not explained why the specific facts of this case cause the scope of the claims to be indefinite.” See HRKACH at pages 4-5 (emphasis provided).
- Accordingly, there are no *per se* rules; only fact-specific analysis.



Relative Terminology: Example

- Claim: An isolated DNA molecule comprising:

* * *

(2) a DNA sequence ... capable of hybridizing to the cDNA encoding SEQ ID NO:2 under **moderately stringent conditions**;

* * *

(based on *Ex parte David Wallach et al.*; Appeal 2007-2228 (BPAI: decided Nov.15, 2007) pages 1-15).

- Is the relative term “moderately stringent conditions” definite ?



Relative Terminology: Example

- Issue: Does the term “moderately stringent” reasonably apprise those skilled in the art of the scope of Appellants’ claimed invention (see *Wallach et al* at page 5)
- Board held the term “moderately stringent conditions” indefinite where:
 1. The term is “... not defined in the disclosure ... “; and
 2. The term has “no well defined meaning in the art” and “can in fact read on a variety of homologues ... “.

See *Wallach et al* at pages 9-10.



Subjective Terminology: Example

- Claim: A method for providing a cosmetic finish on an apparatus glass component comprising:
 - a. providing an apparatus having a glass component;
 - b. depositing a dichroic layer on a first glass component surface; and
 - c. applying an ink layer to a second glass component surface so as to provide an aesthetically pleasing cosmetic finish.
- Specification: does not define “aesthetically pleasing” nor provide a standard for determining a means for evaluating aesthetics in an objective manner.
- In an analogous context, the phrase “aesthetically pleasing” was held indefinite because the meaning of a term cannot depend on the unrestrained, subjective opinion of the person practicing the invention. *Datamize LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347-48, 75 USPQ2d 1801, 1807 (Fed. Cir. 2005).



Markush Claims (Definition)

- A “Markush” claim:
 - recites a list of alternatively useable species; and
 - is commonly formatted as: “selected from the group consisting of A, B, and C”
- However, the phrase “Markush claim” as used in these guidelines means any claim that recites a list of alternatively useable species regardless of format.
- See Supplemental 112 Guidelines.



Markush Claim (Improper Markush Grouping Rejection)

- A Markush claim may be rejected under the judicially approved “improper Markush grouping” when the claim contains an improper grouping of alternatively claimed species in which:
 - (1) the species do not share a “single structural similarity,”
 - or
 - (2) the species do not share a common use
 - e.g. they are not disclosed in the specification to share a common use or known in the art to be functionally equivalent.
- If (1) or (2) apply, then an “Improper Markush Grouping” rejection is proper.
 - case-by-case nature of the inquiry.



MPEP § 803.02: Markush Claims

- MPEP § 803.02 explains that a Markush grouping is proper when the embodiments of the invention share both a common use and a substantial structural feature essential to that use. See *Ex parte Hozumi*, 3 USPQ2d 1059 (B.P.A.I. 1984).
- Thus a proper Markush group possessing a “single structural similarity” means the members possess:
 1. a substantial structural feature (prong 1),
 2. from which the common use must flow (prong 2).
- If a claim that includes a Markush grouping which reads on two or more patentably distinct inventions, a provisional election of species requirement may be made at the examiner’s discretion. *Supplemental Guidelines*.



Improper Markush Claim (Analysis)

- Analyze the claim as a whole and determine whether the alternative species share a common use and a substantial structural feature essential to that use.
- If the species lack either:
 - a common substantial structural feature or
 - a common use; or
 - if the shared structural feature is not essential to the common use,
 - then a rejection on the basis that the claim contains an “improper Markush grouping” is appropriate.
- use Form ¶ 8.40 Improper Markush Grouping Rejection.



Form ¶ 8.40 Improper Markush Grouping Rejection

Claim[1] rejected on the judicially-created basis that it contains an improper Markush grouping of alternatives. See *In re Harnisch*, 631 F.2d 716, 721-22 (CCPA 1980) and *Ex parte Hozumi*, 3 USPQ2d 1059, 1060 (Bd. Pat. App. & Int. 1984). The improper Markush grouping includes species of the claimed invention that do not share both a substantial structural feature and a common use that flows from the substantial structural feature. **The members of the improper Markush grouping do not share a substantial feature and/or a common use that flows from the substantial structural feature for the following reasons:** [2]. In response to this rejection, Applicant should either amend the claim(s) to recite only individual species or grouping of species that share a substantial structural feature as well as a common use that flows from the substantial structural feature, or present a sufficient showing that the species recited in the alternative of the claims(s) in fact share a substantial structural feature as well as a common use that flows from the substantial structural feature. This is a rejection on the merits and may be appealed to the Board of Patent Appeals and Interferences in accordance with 35 U.S.C. §134 and 37 CFR 41.31(a)(1) (emphasis provided).

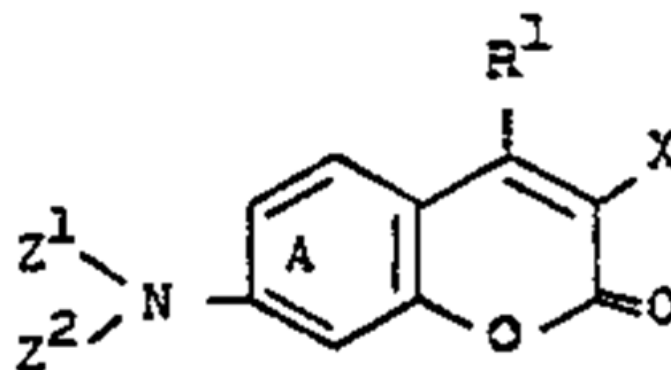
Examiner Note:

1. In bracket 1, insert claim number(s) and “is” or “are” as appropriate.
2. In bracket 2, explain why these species do not share a substantial structural feature as well as a common use that flows from the substantial structural feature.
3. If an election of species requirement is appropriate, this form paragraph can only be used after applicant has made an election.



Markush Grouping: Example 1 : (*In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980)).

- Claim 1: Coumarin compounds which correspond to the general formula



wherein

X represents aldehyde, azomethine, or hydrazone,

R¹ represents hydrogen or alkyl,

Z¹ represents hydrogen, alkyl, cycloalkyl, aralkyl, aryl or a 2- or 3-membered alkylene radical connected to the 6-position of the coumarin ring and

Z² represents hydrogen, alkyl, cycloalkyl, aralkyl or a 2- or 3-membered alkylene radical connected to the 8-position of the coumarin ring and wherein

Z¹ and Z² conjointly with the N atom by which they are bonded can represent the remaining members of an optionally benz-fused heterocyclic ring which, like the ring A and the alkyl, aralkyl, cycloalkyl and aryl radicals mentioned, can carry further radicals customary in dye-stuff chemistry.



Example 1: *Harnisch* Cont.

- CCPA held that the Markush grouping was proper:
 1. All of the claimed compounds are dyes, even if some might also be seen as synthetic intermediates.
 2. Despite the significant variation in functional groups, all of the compounds shared “a single structural similarity” which is the coumarin core.
- Note: here the CCPA stressed that the claimed compounds possessed a substantial structure feature (e.g. coumarin core) which resulted in a common use (e.g. as dyes).



PCT-Unity of Invention: Markush Practice

- PCT International Search and Preliminary Examination Guidelines (ISPE) at http://www.wipo.int/pct/en/texts/pdf/ispe_iii.pdf.
- Chapter 10.17 “Unity of Invention” ; “Markush Practice” : Rule 13.2
 - Unity is met where alternatives of chemical compounds

(A) All have a common property or activity, and

(B)(1) a common structure is present, that is, a significant structural element is shared by all of the alternatives, or

B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

❖ Similar to U.S. “Markush Practice”.



Markush Grouping: Example 2: PCT Guidelines (ISPE Example 24)

Claim 1: A pharmaceutical compound of the formula: A—B—C—D—E, wherein

A is selected from C₁-C₁₀ alkyl or alkenyl or cycloalkyl, substituted or unsubstituted aryl or C₅-C₇ heterocycle having 1-3 heteroatoms selected from O and N;

B is selected from C₁-C₆ alkyl or alkenyl or alkynyl, amino, sulfoxy, C₃-C₈ ether or thioether;

C is selected from C₅-C₈ saturated or unsaturated heterocycle having 1-4 heteroatoms selected from O, S or N or is a substituted or unsubstituted phenyl;

D is selected from B or a C₄-C₈ carboxylic acid ester or amide; and

E is selected from substituted or unsubstituted phenyl, naphthyl, indolyl, pyridyl, or oxazolyl.



Example 2: Cont.

- **Improper Markush Group:**
 1. This claim reads on approximately 2.564×10^{23} possible species;
 2. There is no *substantial* structural feature shared by all species, and
 3. There is no indication that the species share a specific common utility.
 4. Further, the compounds do not belong to a recognized class of chemical compounds.
- One of ordinary skill in the art would expect that the various members within the claim scope would have distinct pharmaceutical activities. The methyl group of A does not define a specific pharmaceutical activity and each of the alternatives set forth under B-E would be expected to impart a different pharmaceutical activity to the compound as a whole.



Markush Group Example 3: No Common Chemical Structure in Composition Claim (ISPE Example 23)

Claim 1: A herbicidal composition consisting essentially of an effective amount of the mixture of

(A) 2,4-D(2,4-dichloro-phenoxy acetic acid) and

(B) a second herbicide selected from the group consisting of copper sulfate, sodium chlorate, ammonium sulfamate, sodium trichloroacetate, dichloropropionic acid, 3-amino-2,5-dichlorobenzoic acid, diphenamid (an amide), ioxynil (nitrile), dinoseb (phenol), trifluralin (dinitroaniline), EPTC (thiocarbamate), and simazine (triazine) along with an inert carrier or diluent.

ISPE Example 23



Example 3 Cont.:

- **Improper Markush Group** since the components under B:
 - do not share any substantial structural feature that results in a common utility; and/or
 - are drawn to different classes of chemical compounds:
 - (a) inorganic salts: copper sulfate sodium chlorate ammonium sulfamate
 - (b) organic salts and carboxylic acids: sodium trichloroacetate dichloropropionic acid 3-amino-2,5-dichlorobenzoic acid
 - (c) amides: diphenamid
 - (d) nitriles: ioxynil
 - (e) phenols: dinoseb
 - (f) amines: trifluralin
 - (g) heterocyclic: simazine



Example 4: Multiple Structurally and Functionally Unrelated Polynucleotides (ISPE Example 32)

- Claim 1. An isolated polynucleotide selected from the group consisting of nucleotide sequences SEQ ID Nos: 1-10.
- Specification: teaches that SEQ ID Nos 1-10 are 500 bp cDNAs obtained from human liver. The sequences are not homologous to each other. Although, they can be used as probes to obtain full-length DNAs, there is no description of the function or biological activity of the corresponding proteins.
- NOTE: The above polynucleotides would be a proper Markush Group if they have a common property or activity and share a substantial structural feature.



Example 4: Multiple Structurally and Functionally Unrelated Polynucleotides Cont.

- Analysis:
 1. The polynucleotides fail to share a common property or activity.
 - A probe (or primer) of SEQ ID NO 1 could not be used to isolate (or amplify) SEQ ID No's 2-10.
 2. The polynucleotides fail to share a substantial structural feature.
 - The sugar phosphate backbone of a nucleic acid chain is not considered to be a substantial structural feature since it is shared by all nucleic acid molecules. No other regions of homology are described.
- NOTE: Isolation of the polynucleotides from a single source (human liver) is not sufficient to meet the criteria for a proper Markush Group.
- Conclude: The polynucleotides are NOT a proper Markush Group.



Example 5: Multiple Structurally and Functionally Related Polynucleotides (ISPE Example 33)

- Claim 1. An isolated polynucleotide selected from the group consisting of nucleotide sequences SEQ ID Nos: 1-10.
- Specification: SEQ ID Nos: 1-10 share a substantial structural feature and their corresponding mRNAs are expressed only in hepatocytes of patients with disease Y.
- Analysis:
 1. SEQ ID Nos 1-10 share a common property: expression of an mRNA present only in patients afflicted with disease Y; and
 2. SEQ ID Nos 1-10 share a substantial structural feature which may be used as the probe to detect mRNA of patients afflicted with disease Y.
- Conclude: SEQ ID No's 1-10 are a Proper Markush Group.



§ 112 ¶ 4: Improper Dependent Claims

- Requires that dependent claims contain a reference to a previous claim in the same application, specify a further limitation of the subject matter claimed, and necessarily include all the limitations of the previous claim.
- If the dependent claim does not comply with the requirements of §112, ¶4, the examiner should reject the dependent claim under § 112, ¶4 as unpatentable rather than objecting to the claim. Supplemental 112 Guidelines at 7166.



§ 112 ¶ 4 rejection

¶ 7.36 The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

Subject to the [fifth paragraph of 35 U.S.C. 112 prohibiting improper multiple dependent claims], a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.



§ 112 ¶ 4 rejection: cont.

¶ 7.36.01 Claim *** rejected under 35 U.S.C. 112, 4th paragraph, as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends, or for failing to include all the limitations of the claim upon which it depends. ***. Applicant may cancel the claim(s), amend the claim(s) to place the claim(s) in proper dependent form, rewrite the claim(s) in independent form, or present a sufficient showing that the dependent claim(s) complies with the statutory requirements.

Examiner Note for Form Paragraph ¶ 7.36.01

1. In bracket 2, insert an explanation of what is in the claim and why the claim does not contain a further limitation, or identify which limitation of the claim upon which it depends is missing.
2. The U.S. Court of Appeals for the Federal Circuit indicated that although the requirements of 35 U.S.C. 112, 4th paragraph, are related to matters of form, non-compliance with 35 U.S.C. 112, 4th paragraph, renders the claim unpatentable just as non-compliance with other paragraphs of 35 U.S.C. 112 would. See *Pfizer, Inc. v. Ranbaxy Labs., Ltd.*, 457 F.3d 1284, 1291-92 (Fed. Cir. 2006) (holding a dependent claim in a patent invalid for failure to comply with 35 U.S.C. 112, 4th paragraph). Therefore, if a dependent claim does not comply with the requirements of 35 U.S.C. 112, 4th paragraph, the dependent claim should be rejected under 35 U.S.C. 112, 4th paragraph, as unpatentable rather than objecting to the claim. **See also MPEP § 608.01(n), Section III, “Infringement Test” for dependent claims.**
3. This form paragraph must be preceded by form paragraph 7.36.



MPEP § 608.01(n), Section III, “Infringement Test” for dependent claims

- “The test as to whether a claim is a proper dependent claim is that it shall include every limitation of the claim from which it depends (35 U.S.C. 112, fourth paragraph) or in other words that it shall not conceivably be infringed by anything which would not also infringe the basic claim.”
- A dependent claim captures an additional infringer if it is broader than the independent claim in at least one respect.



§ 112 ¶ 4 Example 1: Improper Dependent Claim

Claim 1: Composition comprising A, B, C and D.

Claim 2: The composition of claim 1 comprising A, B and C.

Claim 3: The composition of claim 1 comprising A, B, C and E.

Claims 2 and 3 are improperly dependent:

- I. Do not contain all the elements of claim 1;
- II. They are broader in one respect, by not requiring D.

➤ Thus, one can infringe claims 2 and 3 without infringing claim 1 since to infringe claim 1 the composition must contain D (which is not true for claims 2 and 3).



§ 112 ¶ 4 : Example 2: Proper Dependent Claim

Claim 1. A compound having Formula I.

Claim 2. A composition comprising the compound of Claim 1 and a pharmaceutically acceptable buffer.

- Claim 2 is properly dependent:
 - I. it contains all the limitations of claim 1; i.e. a compound having formula 1.
 - II. it further limits claim 1 by requiring “a pharmaceutically acceptable buffer”.
- Thus, one cannot infringe claim 2 without infringing claim 1.



§ 112 ¶ 4 : Example 3: Improper Dependent Claim

Claim 1. A nucleic acid comprising SEQ ID No 1. (SEQ ID No 1 is 200 nucleotides in length)

Claim 2. A probe comprising a 20-mer fragment of the nucleic acid of Claim 1.

- Claim 2 is an improperly dependent claim:
 - I. Does not contain all the elements of claim 1, e.g. the 200 nucleotide sequence of SEQ ID No. 1;
 - II. Claim 2 is broader in one respect, by encompassing nucleic acid fragments of SEQ ID No. 1, e.g. a 20-mer.
- Thus, one can infringe claim 2 without infringing claim 1.



§ 112 ¶ 6: Means-Plus-Function Claim Limitation: Guidance

- For any claim limitation reciting a term and associated function:
 - I. Determine whether the limitation invokes § 112, ¶ 6
 - ❖ Consider § 112, ¶ 2 rejection when it is unclear whether a claim limitation invokes § 112, ¶ 6.
 - II. If the limitation invokes § 112, ¶ 6,
 - ❖ Interpret the claim scope to “cover the corresponding structure, material, or acts described in the specification and equivalents thereof.”
 - III. If the specification does not disclose the structure (or sufficient structure) for achieving the recited function
 - ❖ Consider rejecting the claim under § 112, ¶ 2 because the claim scope is unclear.



112 ¶ 6: Invoked?

1. Determining whether the limitation invokes §112, ¶ 6

- This is important as the BRI may change depending on whether §112, ¶ 6 is invoked;
- If §112, ¶ 6 is not invoked, the limitation must be interpreted under BRI in light of the specification and the prior art.
 - ◆ The scope of the claim is not limited to the specific structure disclosed in the specification.
 - ◆ Limitations cannot be imported to the claim from the specification.



§112 ¶ 6: Invoked? (cont.)

A. Does the claim limitation use the phrase “means for” or “step for” coupled with functional language?

- If it does, there is a strong presumption that §112, ¶ 6 is invoked;
- This presumption is overcome if the limitation includes the structure necessary to perform the recited function.



§112 ¶ 6: Invoked ? (cont.)

B. Other non-structural terms (a term that is simply a substitute for “means for”) coupled with functional language?

For example, the following can be non-structural terms used in place of “means for”:

- mechanism for
- module for
- Device for
- Unit for
- Component for
- element for
- member for
- apparatus for
- machine for
- system for



§112 ¶ 6: Invoked ? (cont.)

B. Other non-structural terms (a term that is simply a substitute for “means for”) coupled with functional language will invoke §112, ¶6, if:

- » It uses a non-structural term without any structural modifier,
- » The term is modified by functional language, and
- » The limitation does not include the structure necessary to perform the claimed function.



§112 ¶ 6: Corresponding Structure

2. Identifying the corresponding structure disclosed in the specification

- This is important because under the BRI, the claim scope of limitation that invokes §112, ¶ 6 is limited to the structure specifically disclosed in the specification for achieving the recited function and equivalents to that structure;
- How to identify the corresponding structure in the specification?
 - Review the specification from the point of view of one skilled in the art.
 - Determine whether the specification clearly links the structure to the claimed function.
 - Determine whether the disclosure contains sufficient structure to perform the claimed function.



§112 ¶ 6: Lack of (or insufficient) corresponding structure

3. If the specification lacks the corresponding structure (or sufficient structure), the claim must be rejected as indefinite under §112, ¶ 2.

- This is important because if the specification does not disclose sufficient structure to perform the claimed function of a §112, ¶ 6 limitation, the claim scope will not be clear, and will amount to pure functional claiming.
- A bare statement that known techniques can be used is not sufficient to support a §112, ¶ 6 limitation.



§ 112 ¶ 6 Example 1

- Claim 1: A dispenser, comprising:
a piping system is provided with a storage tank for storing liquid;
a storage tank including at least a first liquid tank having a cooling device
and a second liquid tank having a heating device;
a **means for sterilizing said piping system**, said first liquid tank and said
second liquid tank;
- This claim includes “means for...” language that invoke
112/6th paragraph and the examiner must do a 112/6th
paragraph analysis.



§ 112 ¶ 6 Example 2 (Specification)

- Application relates only to nucleic acid compositions and their use in methods for treating skin and other cancers that express elevated levels of “protein X” as compared to normal tissue.
- In accordance with the invention, a therapeutic agent, for example an antisense oligonucleotide or RNAi nucleotide inhibitor with sequence specificity for “protein X” mRNA, for example human “protein X” mRNA, is administered to an individual suffering from skin cancer or some other cancer expressing elevated levels of “protein X” in a therapeutically effective amount.



§ 112 ¶ 6 Example 2 (Claim)

- Claim: A pharmaceutical composition comprising a
 - (a) **means for reducing the amount of active “protein X” in cancerous cells** and
 - (b) a pharmaceutically acceptable carrier.



§ 112 ¶ 6: Example 2 (Analysis)

- Claim 1 : A pharmaceutical composition comprising a
 - (a) means for reducing the amount of active “protein X” in cancerous cells and
 - (b) a pharmaceutically acceptable carrier.
- Analysis:
 1. (A) the claim limitation uses the term “means for”, “step for” or a “non-structural equivalent” (Yes: “means for”) ;
 2. (B) the “means for” or “step for” must be modified by functional language (Yes: “reducing the amount of active ‘protein X’ in cancerous cells”); and
 3. (C) the term “means for” or “step for” must not be modified by sufficient structure, material, or acts for achieving the specified function (Yes: claim 1 lacks structure/material/acts for achieving function).
- Conclude: Claim 1 properly invokes 112 ¶ 6.



§ 112 ¶ 6: Example 2 (Analysis) cont.

- Claim 1: A pharmaceutical composition comprising a
 - (a) means for reducing the amount of active “protein X” in cancerous cells and
 - (b) a pharmaceutically acceptable carrier.

- Since claim 1 properly invokes § 112 ¶ 6, the claim must “be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.”
 - e.g. an antisense oligonucleotide or RNAi nucleotide inhibitor with sequence specificity for “protein X” mRNA and equivalents thereof.

- Note: a prior art reference teaching an equivalent anticipates the claim.



Questions

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